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8EHQ-1204-13888

Great Lakes
CHEMICAL CORPORATION

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U.S. Environmental Protection Agency
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Washington, DC 20460

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Attention: TSCA Section 8(e) Coordinator

RE: Submission of Reproductive and Fetal Survival Effects in the Rat via an OECD 421 Guideline Screening Study on a research and development material of Phenol, isopropylated, phosphate (3:1); (CAS No.: 68937-41-7) [

].
(When responding, please refer to JAB-04-070).

Dear Sir:

Great Lakes Chemical Corporation (GLCC) submits this letter of substantial risk notification in accordance with Section 8(e) of the Toxic Substances Control Act, 15 USC 2607(e), and the Environmental Protection Agency's "Statement of Interpretation and Enforcement Policy" thereof 43 FR 1110, 35 seq., March 16,1978. The notification is in regards to a verbal report and draft Summary Data Tables received from the laboratory that is performing an OECD 421 the Reproduction/ Developmental Toxicity Screening Test of isopropylated triphenyl phosphate (common name) [

],

a research and development material.

The test material was administered via oral gavage using corn oil as the carrier vehicle to a group of 12 male and 12 female rats of the Sprague-Dawley Crl:CD®(SD)IGS BR strain. The test material was given once daily at the dose level of 400 mg/kg. Males were dosed for at least 14 days prior to mating which continued throughout the 14 day mating period and for at least 14 days after completion of the mating period until all conceived females delivered. Females were dosed for at least 14 days prior to mating, throughout mating and continued to be dosed until one day prior to termination (lactation day 4 for those that delivered, post-mating day 25 or post-cohabitation day 25 for those that did not deliver). A concurrent control group of identical design received the carrier vehicle corn oil on a comparable regimen.

The study design included recording F_0 viability and clinical observations, food consumption, body weights, and parturition and litter observations. Macroscopic examinations were conducted on all F_0 animals with tissues and organs collected for microscopic examination

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and relative organ weight determination in accordance with the study protocol. F_1 data included litter identification, pup body weights, and appearance and behavior observations. All F_1 pups were examined macroscopically and preserved intact in Bouin's solution for possible future whole-body visceral evaluation.

Fertility of the test group is considered comparable with that of the control group. All 12 animals were pregnant, as were the animals of the control group. The test group means for number of live, dead and total pups delivered and the mean number of surviving pups at lactation day 4 (study termination) are considered comparable with the control group.

There were statistically significant effects noted for absolute and relative organ weights in test females, when compared to the control. The mean absolute and relative liver weights were increased and the significant differences were $p<0.01$ and $p<0.05$ for absolute and relative, respectively. No absolute and/or relative organ weight differences were noted for test males.

Sincerely,

John A. Biesemeier
Manager, Regulatory Toxicology
Regulatory Affairs

JAB/jab